



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

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Washington, D.C. 20231

09/144,502

SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

David Fitzgerald (PTO)

Gordon Kit (attorney)

Date of interview: **19 April 1999** Type: ☒ Telephone/fax ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative)

Exhibit shown or demonstration conducted: ☐ Yes ☒ No Attachment(s): ☐ Yes ☒ No

If yes for either, brief description:

Agreement ☐ was reached with respect to some or all of the claims in question ☐ was not reached. n/a

Claims discussed: Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

This paper recapitulates the remarks in the examiner's reasons for allowance (Paper No. 14) and is entered to clarify the record with respect to the interview conducted on the date noted.

Formal matters relating to the application were discussed. The examiner pointed out the respects in which the preliminary amendment filed 09 October 1998 (Paper No. 6) failed to comply with 37 C.F.R. § 1.121(b) and indicated the parts of the amendment which had consequently not been entered. The examiner indicated how the amendment could be revised to comply with the rule, and Mr. Kit agreed to provide a revised amendment in proper form.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 enumerated in M.P.E.P. § 713.04). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections, and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.



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EXAMINER

ART UNIT

PAPER NUMBER

~~18~~ 16

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

David Fitzgerald (PTO)

Gordon Kit (attorney)

Date of interview: **05 May 1999** Type: ☒ Telephone/fax ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative)

Exhibit shown or demonstration conducted: ☐ Yes ☒ No Attachment(s): ☐ Yes ☒ No

If yes for either, brief description:

Agreement ☒ was reached with respect to some or all of the claims in question ☐ was not reached.

Claims discussed: Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

This paper recapitulates the remarks in the examiner's reasons for allowance (Paper No. 14) and is entered to clarify the record with respect to the interview conducted on the date noted.

The examiner indicated that claims 1-17 were not allowable, as discussed in detail in Paper No. 14. Mr. Kit indicated that his clients had consented to the cancellation of claims 1-17 by examiner's amendment.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 enumerated in M.P.E.P. § 713.04). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections, and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.



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EXAMINER

ART UNIT	PAPER NUMBER
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~~16~~ 17

DATE MAILED:

EXAMINER INTERVIEW SUMMARY RECORD

All participants (applicant, applicant's representative, PTO personnel):

David Fitzgerald (PTO)

Gordon Kit (attorney)

Date of interview: **27 May 1999** Type: ☒ Telephone/fax ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative)

Exhibit shown or demonstration conducted: ☐ Yes ☒ No Attachment(s): ☐ Yes ☒ No

If yes for either, brief description:

Agreement ☐ was reached with respect to some or all of the claims in question ☐ was not reached. n/a

Claims discussed: Identification of prior art discussed:

Description of the general nature of what was agreed to if an agreement was reached, or any other comments:

This paper recapitulates the remarks in the examiner's reasons for allowance (Paper No. 14) and is entered to clarify the record with respect to the interview conducted on the date noted.

Formal matters relating to the application were discussed. The examiner first indicated that a supplemental reissue declaration would be required in view of the examiner's amendment approved on 05 May 1999 because cancellation of the original claims would constitute rectification of a reissue "error" within the meaning of the rules. The examiner indicated the nature of the representations required by a supplemental declaration according to 37 C.F.R. § 1.75(b)(1). Mr. Kit agreed to supply a supplemental declaration.

The examiner also requested copies of the references cited in the Disclosure Statement filed 31 August 1998 which were cited only in applications to which the instant application does not claim priority (37 C.F.R. § 1.98(a), (d)). Mr. Kit felt that it would be easiest to simply provide copies of all of the cited art.

Lastly, the examiner requested that a separate letter requesting deletion of Figs. 2A-B and 3A-B, as required by 37 C.F.R. § 1.121(b)(3)(ii), be filed, and Mr. Kit agreed to provide such a letter.

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

☒ 1. It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph below has been checked to indicate to the contrary, A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW (e.g., items 1-7 enumerated in M.P.E.P. § 713.04). If a response to the last Office action has already been filed, then applicant is given one month from this interview date to provide a statement of the substance of the interview.

☐ 2. Since the examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections, and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the substance of the interview unless box 1 above is also checked.

EXAMINER'S AMENDMENT

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the Issue Fee. Authorization for this Examiner's Amendment was given in a telephone interview with Gordon Kit on 05 May 1999.

Cancel claims 1-17.

REASONS FOR ALLOWANCE

The following is an Examiner's Statement of Reasons for Allowance. Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably **accompany** the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

This application was prosecuted by telephone, and this communication summarizes the conversations relating to the claims between the undersigned and applicant's representative, Gordon Kit, in April and May of 1999. The nature and substance of discussions relating to the satisfaction of various formal requirements involving the reissue will be evident from the several preliminary submissions filed in the application. In particular, the telephone interviews between the examiner and Mr. Kit on 19 April 1999 (cited by counsel in Paper No. 7) and 27 May 1999 (cited in Nos. 11, 12, and 13) are accurately summarized by counsel's remarks in the noted papers.

The examiner expressed concerns involving patented claims 1-17. Insofar as the independent claims recite language which is on its face broad, the written description does not appear to identify or describe a number of species which is representative of the genus suggested by the language. However, in remarks accompanying the amendment filed 12 August 1996 in the application which issued as Patent No. 5,712,155, serial no. 08/346,555, counsel urged that the hybridization limitation of independent claims 1, 2, 3, and 15 (as issued) was functional language expressly authorized by 35 U.S.C. § 112, sixth paragraph. '555 application, Paper No. 6 at pages 5-6. The product claims would thus be construed to embrace only the corresponding structures

or materials and their equivalents described in the specification which effect the recited function. *Sage Products Inc. v. Devon Indus. Inc.*, 126 F.3d 1420, __, 44 U.S.P.Q.2d 1103, 1110 (Fed. Cir. 1997). However, each of claims 1, 2, 3, and 15 is directed to a single product, viz., a "sequence." None is directed to a combination of elements, as is prerequisite to the application of § 112, sixth paragraph. It is therefore not clear how the claims should be construed or, consequently, what their scope is. Applicant has agreed to cancel original claims 1-17 in favor of the new claims presented in the instant reissue.

No prior art was made of record in the file of the '155 patent. Applicant has cited all of the references which are of record in sibling case 08/650,000 as well as references of record in several related applications, as applicant indicates in Paper No. 5. The '000 application, examined by the undersigned and now allowed, contains claims directed to polypeptides which correspond to the nucleic acid claims allowed in the present reissue application. The latter patentably define over the prior art of record because no nucleic acid encoding a p75/p80 TNFR was described or identified in the art prior to the instant invention. Moreover, no complete structure (sequence) of any such receptor polypeptide, which would arguably render obvious the genus of nucleic acids encoding it, was known prior to the invention. In this regard, the closest prior art is Engelmann *et al.* (*JBC* 265: 1531-36, 25 January 1990), which discloses the purification to near-homogeneity of two TNF-binding proteins from human urine. The second of those has the N-terminal amino acid sequence Val-Ala-Phe-Thr-Pro-, identical to residues 5-9 of instant SEQ ID NO: 2 (abstract). The prior art N-terminal sequence does not suffice to place either the nucleic acids instantly claimed or the structures of the polypeptides they encode in the hands of the artisan.

The terminal disclaimer filed on 25 July 1997 in application serial no. 08/346,555 and recorded therein, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 5,395,760, has been recorded in the instant reissue application.

The amendment filed 9 October 1998 was entered only to the extent that it complied with 37 C.F.R. § 1.121(b). The amendment filed 19 April 1999, which fully complies with § 1.121(b), rectifies grammatical informalities in the new claims and cancels the figures setting

forth sequences in favor of those in the sequence listing. The sequences themselves remain unchanged relative to the original patent.

The supplemental reissue declaration filed 28 May 1999 (which acknowledges the amendment effected by the instant examiner's amendment) complies with 37 C.F.R. § 1.175(b)(1).

The art cited but not relied upon is considered pertinent to applicant's disclosure. Feldmann *et al.* (U.S. Patent No. 5,863,786), claiming priority to a PCT application filed after the instant invention, describes and claims nucleic acids encoding truncated TNF-binding TNFR polypeptides having the first three but not the fourth of the Cys-rich domains in the extracellular domains of the native receptors. With reference to the human p75 TNFR, such polypeptides correspond to residues 17-140 of instant SEQ ID NO: 2. '786, Fig. 6. The specification of the Feldmann patent expressly places polypeptides comprising any more than one residue of the contiguous native p75 TNFR sequence C-terminal to residue 140 without the invention it claims. '786, col. 3, last paragraph. Compare instant Example 6.

Any inquiry concerning this communication should be directed to David Fitzgerald, who can be reached by any of the following means:

Telephone (703) 308-3934

Fax

All formal papers (703) 308-4242

Informal communications (703) 308-0294

e-mail (note PTO policies below) david.fitzgerald@uspto.gov

Inquiries of a general nature should be directed to the Technology Center 1 receptionists at (703) 308-0196.



DAVID L. FITZGERALD

PRIMARY EXAMINER

ART UNIT 1646

19 June 1999

The best time to reach **Examiner Fitzgerald** is from 9 a.m. to 4 p.m. (Eastern). If he cannot take a call, a message may be left on his voicemail. Should attempts to reach him be unsuccessful, the acting supervisor for this Art Unit, Paula Hutzell, may be reached at (703) 308-4310.

Most official papers and all informal **communications may be submitted to the PTO by fax**. For specific policies, refer to 37 C.F.R. § 1.6 and the notice published at 1096 O.G. 30. To facilitate their receipt and handling, please —

- ♦ Call the examiner when you send an urgent communication.
- ♦ **Do not send a duplicate copy** by mail or courier.

Any Internet **e-mail communications will be made of record in the application file**. PTO employees cannot engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. § 122. This policy is more fully set forth in the Interim Internet Usage Policy published in the PTO's *Official Gazette* on 25 February 1997 at 1195 O.G. 89.